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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,606	03/18/2004	Susan K. Brown-Skrobot	VTN-5054	5871

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EXAMINER
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STITZEL, DAVID PAUL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/803,606	<b>Applicant(s)</b> BROWN-SKROBOT ET AL.	
	<b>Examiner</b> David P. Stitzel, Esq.	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**OFFICIAL ACTION**

***Acknowledgment of Receipt***

Receipt of the Applicant's Response, which was filed on July 14, 2006, in response to the Official Action dated January 25, 2006, is acknowledged.

***Status of Claims***

Claim 1 was amended, and claims 15, 16, 18 and 19 were cancelled by an amendment that accompanied the aforementioned Response. As a result, claims 1-14 and 17 are currently pending and therefore examined herein on the merits for patentability.

***Claim Rejections - 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regard as the invention. With respect to claim 1, confusion exists as to what constitutes "sufficiently" and "substantially prevented?" More specifically, the term/phrase "sufficiently" and "substantially prevented" are relative terms/phrases that render claim 1 indefinite. The term/phrase "sufficiently" and "substantially prevented" are not defined within said claim, the instant specification does not appear to provide a standard for ascertaining the requisite degree of what constitutes "sufficiently" and "substantially prevented," and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention. Claims 2-14 and 17, which are dependent upon and include all of the limitations of independent claim 1, are therefore likewise rejected under 35 U.S.C. § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Appropriate correction is required.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,320,843 (hereinafter the Raheja '843 patent).

With respect to claims 1-3 and 6 of the instant application, the Raheja '843 patent discloses an injection or blow molded antibacterial article, such as an antibacterial contact lens case, for storing a contact lens immersed in an antibacterial ophthalmic solution, wherein said molded antibacterial article comprises a thermoplastic polyolefin resin, such as polyethylene, polypropylene, or a mixture thereof, having incorporated therein a titanium oxide colorant and an antimicrobial metal ion, wherein said antimicrobial metal ion leaches from said thermoplastic polyolefin resin into said antibacterial ophthalmic solution (abstract; column 2, lines 1-68; column 3, lines 21-47; column 4, lines 45-68, Examples 1 and 2; column 5, lines 1-9, Example 2 continued; column 7, lines 65-68; claims 1, 2, 7, 8, 12, 13, 18 and 19).

Claims 1-3 and 6 of the instant application recite that said package comprises: a contact lens; a solution; and a base element; wherein said contact lens, said solution, or both comprise a pharmaceutical agent or an antimicrobial agent; wherein said base element has incorporated therein a

titanium dioxide opacifying agent, which blocks light sufficiently so that the reaction of light with the pharmaceutical agent, antimicrobial agent, or both is substantially prevented. The claimed limitation of a titanium dioxide opacifying agent that blocks light sufficiently so that the reaction of light with the pharmaceutical agent, antimicrobial agent, or both is substantially prevented is a recitation of an intended future use of said composition and will therefore be given little probative patentable weight. Moreover, a recitation of an intended future use of the claimed invention must result in a patentably distinct difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art composition is capable of performing the intended use of the claimed invention, then the prior art composition anticipates the claimed invention. Since the Raheja '843 patent discloses incorporating into said molded antibacterial article a titanium oxide colorant, which is identical to the titanium dioxide opacifying agent of the claimed invention, the prior art composition is capable of performing the intended future use of the claimed invention. As a result, the Raheja '843 patent anticipates said claims.

The "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); and MPEP § 2112. Furthermore "products of identical chemical composition can not have mutually exclusive properties," since a chemical composition and its properties are inseparable. See *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP § 2112.

2. The rejection of claims 1, 10 and 11 under 35 U.S.C. § 102(b) as being anticipated by International Application Publication WO 02/44260 (hereinafter the Portnoy '260 publication) is hereby withdrawn in light of the instant claim amendments incorporating limitations of a contact lens, a solution, or both comprising a pharmaceutical agent or an antimicrobial agent.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 4, 5, 7 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of U.S. Pre-Grant Patent Application Publication 2002/0136899 (hereinafter the deRojas '899 publication).

The teachings of the Raheja '843 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 4, 5, 7 and 8 of the instant application, although the Raheja '843 patent teaches incorporating a titanium oxide colorant into a molded antibacterial article for storing a contact lens in an ophthalmic solution, the Raheja '843 patent does not explicitly teach incorporating a photochromic compound as an opacifying agent into said article. However, the deRojas '899 publication teaches coating and spraying a contact lens with a photochromic compound, selected from a spirooxazine, naphthopyran, chromene (a.k.a., benzopyran), spiroindolinonaphthoxazine, or a combination thereof, so as to prevent darkening of the contact lens by imparting protection from

ultraviolet radiation ([0015]-[0018], [0020], [0037]-[0039]). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the molded antibacterial article comprising polyethylene and/or polypropylene, of the Raheja '843 patent, by coating and spraying a photochromic compound onto said molded antibacterial article so as to impart protection from ultraviolet radiation and thereby prevent darkening of the contact lens contained therein, as reasonably suggested by the deRojas '899 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to coat and spray a photochromic compound onto said molded antibacterial article so as to impart protection from ultraviolet radiation and thereby prevent darkening of the contact lens contained therein, especially since said molded antibacterial article comprises polyethylene and/or polypropylene, which are transparent thermoplastic polyolefin resins.

2. Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of U.S. Patent 6,054,090 (hereinafter the Duis '090 patent).

The teachings of the Raheja '843 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claim 9 of the instant application, although the Raheja '843 patent teaches incorporating a titanium oxide colorant or pigment into a molded antibacterial article for storing a contact lens in an ophthalmic solution, the Raheja '843 patent does not explicitly teach printing an opacifying agent onto a surface of said article. However, the Duis '090 patent teaches a contact lens container having a label printed thereon, wherein said label comprises a dye (column 1, lines 10-21; column 2). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the molded antibacterial article, of the Raheja '843 patent,

having a titanium oxide colorant or pigment incorporated therein, by alternatively printing a label comprising a dye, as reasonably suggested by the Duis '090 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to print a label onto said molded antibacterial article so as to provide a label thereon bearing a coating of a desired dye, colorant or pigment.

3. Claims 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of U.S. Pre-Grant Patent Application Publication 2002/0046958 (hereinafter the Lipscomb '958 publication).

The teachings of the Raheja '843 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 12 and 13 of the instant application, although the Raheja '843 patent teaches incorporating a titanium oxide colorant or pigment into a molded antibacterial article equipped with a sealable cap for storing a contact lens in an ophthalmic solution, the Raheja '843 patent does not explicitly teach a flexible cover sheet comprising an adhesive laminate of aluminum foil and polypropylene. However, the Lipscomb '958 publication teaches a molded container for storing a silicone hydrogel contact lens comprising polyethylene and/or polypropylene, wherein said molded container is equipped with a flexible cover sheet comprising a laminate of a metal foil layer and a heat sealed polyethylene layer (abstract, [0048], [0051]). Although the Lipscomb '958 publication does not explicitly teach polypropylene, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute polypropylene for polyethylene, as said polyolefins are routinely used interchangeably within the art due to their substantially identical chemical properties. It would have been prima facie obvious to one of ordinary skill in the art at the



time the instant application was filed to modify the sealable cap of the Raheja '843 patent with the flexible cover sheet of the Lipscomb '958 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to utilize a flexible cover sheet with said molded antibacterial article, of the Raheja '843 patent, so as to seal and maintain the ophthalmic solution therein, as reasonably suggested by the Lipscomb '958 publication.

4. Claims 14 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of the Lipscomb '958 publication and in further view of U.S. Pre-Grant Patent Application Publication 2003/0044447 (hereinafter the Zanini '447 publication).

The teachings of the Raheja '843 patent and the Lipscomb '958 publication are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 14 and 17 of the instant application, although the Lipscomb '958 publication teaches incorporating silicone hydrogel contact lenses into the molded container comprising polyethylene and/or polypropylene, wherein said molded container is equipped with a flexible cover sheet comprising a laminate of a metal foil layer and a heat sealed polyethylene layer (abstract, [0048], [0051]), the Lipscomb '958 publication does not explicitly teach either a specific species of silicone hydrogel contact lens, or a pharmaceutical agent, incorporated therein. However, the Zanini '447 publication teaches a molded antimicrobial container for storing a silicone hydrogel contact lens comprising transparent polyolefins, such as polyethylene and/or polypropylene; wherein said silicone hydrogel contact lens is formulated from balafilcon A and lotrafilcon A; wherein said antimicrobial component of said molded antimicrobial container is useful for reducing adverse effects associated with microbial production including, but not limited to, ocular inflammation, ocular ulcers, red eye, and microbial keratitis ([0226], [0227], [0228], [0232], [0300]-[0306]). It would have been

obvious to one of ordinary skill in the art at the time the instant application was filed to incorporate silicone hydrogel contact lenses into said molded container, as taught by the Lipscomb '958 publication, that are formulated from balafilcon A and lotrafilcon A, as reasonably suggested by the Zanini '447 publication. One of ordinary skill in the art would have been motivated, as well as had a reasonable expectation of success, to incorporate said silicone hydrogel contact lenses formulated from balafilcon A and lotrafilcon A, as taught by the Zanini '447 publication, into the molded antibacterial article comprising a thermoplastic polyolefin resin, such as polyethylene and/or polypropylene of the Raheja '843 patent, as the Zanini '447 publication likewise teaches incorporating said silicone hydrogel contact lenses formulated from balafilcon A and lotrafilcon A into a molded antimicrobial container for storing a silicone hydrogel contact lens comprising transparent polyolefins, such as polyethylene and/or polypropylene.

5. Claims 10 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of International Patent Application Publication WO 02/44260 (hereinafter the Portnoy '260 publication).

The teachings of the Raheja '843 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 10 and 11 of the instant application, although the Raheja '843 patent teaches an injection or blow molded antibacterial article, such as an antibacterial contact lens case, for storing a contact lens immersed in an antibacterial ophthalmic solution, wherein said molded antibacterial article comprises a thermoplastic polyolefin resin, such as polyethylene, polypropylene, or a mixture thereof, the Raheja '843 patent does not explicitly teach that said molded antibacterial article (i.e., contact lens case) comprises a metallocene catalyzed polymer or copolymer of polypropylene

and/or polyethylene, as claimed in claims 10 and 11. However, the Portnoy '260 publication teaches an injection molded contact lens package comprising a metallocene catalyzed monomer or copolymer of polypropylene and/or polyethylene, having an additive incorporated therein, wherein said additive may include, but is not limited to, a colorant, a whitening agent, and a biostabilizer (abstract; page 1, lines 1-16; page 2, lines 29-32; page 3, lines 1-9; page 4, lines 1-5 and 15-19; page 5, lines 7-9; page 6, lines 22-28; page 23, lines 1-4; page 26, lines 4-8 and 12-22). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the molded antibacterial article (i.e., an antibacterial contact lens case for storing a contact lens immersed in an antibacterial ophthalmic solution) of the Raheja '843 patent, which comprises a thermoplastic polyolefin resin, such as polyethylene, polypropylene, or a mixture thereof, by incorporating therein a metallocene catalyzed monomer or copolymer of polypropylene and/or polyethylene, as taught by the Portnoy '260 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate a metallocene catalyzed monomer or copolymer of polypropylene and/or polyethylene for the thermoplastic polyolefin resin (i.e., polyethylene, polypropylene, or a mixture thereof) of the antibacterial contact lens case of the Raheja '843 patent, since the Portnoy '260 publication teaches that metallocene catalyzed monomers or copolymers of polypropylene and/or polyethylene are particularly useful when manufacturing articles that require dimensional accuracy and precision, such as a contact lens package. One of ordinary skill in the art would have had a reasonable expectation of success in incorporating a metallocene catalyzed monomer or copolymer of polypropylene and/or polyethylene for the thermoplastic polyolefin resin (i.e., polyethylene, polypropylene, or a mixture thereof) of the antibacterial contact lens case of the Raheja '843 patent, since it would have been prima facie obvious to one of ordinary skill in the art that a "contact lens package," as taught by the Portnoy '260 publication, would intrinsically include a contact

lens case having contained therein an ophthalmic solution and a contact lens immersed within said ophthalmic solution.

***Examiner's Response to Applicant's Remarks***

Although Applicants' arguments as set forth in the aforementioned Response have been fully considered in light of the claims as currently amended, they are not persuasive. Applicants' claim amendments necessitated the new grounds of rejection as set forth hereinabove.

Applicants argue on pages 5 and 6 of the aforementioned Response, that the Raheja '843 patent fails to disclose at least one element of the claimed invention, as currently amended. More specifically, Applicants argue that the Raheja '843 patent fails to disclose a contact lens comprising a pharmaceutical agent or an antimicrobial agent that is susceptible to degradation upon exposure to light. In response to Applicants' arguments, the at least one element (i.e., contact lens) of the claimed invention to which Applicants are referring to is claimed in the alternative, that is "the contact lens, solution or both" as recited within claim 1 as currently amended. Therefore, the limitations of claim 1 as currently amended are met if *either* the contact lens, *or* the solution, *or* both the contact lens and the solution, comprise a pharmaceutical agent or an antimicrobial agent. Applicants acknowledge in the last paragraph of page 5 in the remarks section of the aforementioned Response that "In fact, the '843 patent teaches 'providing an article molded from a plastic resin including an inorganic carrier retaining antibacterial metal ions, and placing the ophthalmic solution in contact with the article' so that the 'metal ions leach from the resin to the ophthalmic solution,'" thereby providing a solution comprising an antimicrobial agent, as instantly claimed.

Applicants also argue on pages 5 and 6 of the aforementioned Response, that the Raheja '843 patent fails to disclose a contact lens case comprising an opacifying agent that blocks light from reacting with said pharmaceutical agent or said antimicrobial agent within said contact lens. In

response to Applicants' arguments, since the Raheja '843 patent discloses incorporating into said molded antibacterial article a titanium oxide colorant, which is identical to the titanium dioxide opacifying agent of the claimed invention, the prior art composition is capable of performing the intended future use of the claimed invention. As a result, the Raheja '843 patent anticipates said claims. The "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); and MPEP § 2112. Furthermore "products of identical chemical composition can not have mutually exclusive properties," since a chemical composition and its properties are inseparable. See *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP § 2112.

### ***Conclusion***

Applicants' claim amendments necessitated the new grounds of rejection presented in this Official Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from

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Examiner: David P. Stitzel, Esq.

the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


***Contact Information***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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